REMARKS

Claims 1-2 and 4-14, as amended, are currently pending in the application, as amended. Claim 1 has been amended to incorporate the language of claim 3. Claim 3 has therefore been cancelled without prejudice. Claim 7 has been rewritten in independent form to include the language of the original base claims, claims 1 and 6. The depending of claim 4 has been changed. Accordingly, no new matter has been added as a result of the above amendments.

Applicants respectfully request that the Amendment After Final Rejection be entered in accordance with 37 C.F.R. § 714.13, because: (1) no new matter has been added to the application by the Amendment After Final; (2) the Amendment After Final addresses and resolves all issues raised by the Examiner in the final Office Action; (3) the subject matter of the Amendment After Final has already been included in the Examiner's search and, therefore, does not require the Examiner to perform further searching; (4) the Amendment After Final places the application in condition for allowance or in better form for appeal and (5) the Amendment After Final does not result in a net addition to the claims of the application.

Claim Rejection 35 U.S.C. § 102

The Examiner rejected claims 1-8, 10, 13 and 14 under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,827,262 (Neftel). Applicants respectfully traverse this rejection.

Referring to Figs. 1-18b, Neftel discloses several embodiments of a syringe device for mixing two compounds. The syringe devices include a sleeve 14, 14''' for mounting between a syringe 12, 12' and a vial 10, 10' and two compounds, typically a fluid in the syringe 12, 12' and a powder in the vial 10, 10' are mixed by creating a fluid path between the syringe 12, 12' and the vial 10, 10'. Referring to Figs. 1-18b, in each of the embodiments of the syringe devices of Neftel, with the exception of the syringe device of the embodiments of Figs. 3, 4 and 13, a needle 34 is mounted directly to the syringe 12, 12' and does not detach from the syringe 34 before, during or after being mounted to the sleeve 14, 14'''. In the embodiment of Figs. 3 and 4, the needle is replaced by a tubular segment 60 with perforating ends 62, 64, which is fixedly mounted on radial fins 66. The radial fins 66 are slidingly mounted within the sleeve 14 such that the syringe vial 12 is inserted into the sleeve 14 until the tubular segment 60 pierces the vial

cap 70 of the syringe vial 12. The syringe vial 12 then contacts the radial fins 66 and moves the radial fins 66 until the opposing end of the tubular segment 60 pierces the septum 22 of the vial 10. The tubular piece 60 is fixed in position relative to the radial fins 66. Referring to the embodiment of Fig. 13, the syringe 12′ includes a cylindrical adapter 246 fixedly mounted to its barrel, making the adapter 246 an integral component of the syringe so that removal of the adapter 246 would clause fluid to flow out of the open end of the barrel syringe. The cylindrical adapter 246 includes a frustoconical end 246b that releasably receives a head 248 of the needle 34′ and the needle 34′ includes ribs 254 extending therefrom. A portion or flange 260 extends inwardly from an inner surface of a guide piece 14a of the sleeve 14 and selectively engages the ribs 254 to prevent the needle 34′ from being removed from the sleeve 14 when the syringe 12′, including the fixedly mounted cylindrical adapter 246, is removed from the sleeve 14.

Referring to Figs. 1-4 and 9, the present application is directed to a syringe safety device 10 that is configured to form a fluid coupling between a sealed vial 12 and a syringe 24. The syringe safety device 10 includes a tubular connector 18 having opposing first and second open axial ends 18a, 18b and a sliding joint 22 that is received in the second open axial end 18b of the tubular connector 18. The first open axial end 18a of the tubular connector 18 is adapted to engage an end of the medicine vial 12 with a stopper 14 therein. The sliding joint 22 includes opposing first and second open axial ends 22a, 22b and a passageway extending between the first and second axial ends 22a, 22b. The first open axial end 22a of the sliding joint 22 is adapted to engage with an enlarged blunt mounting end 20b of a syringe needle 20 which is not attached to a syringe. The second axial end 22b of the sliding joint 22 is adapted to releasably engage a releasable needle receiver 30 on a distal end of a barrel of the syringe 24 without a needle attached thereto. The syringe 24 is releasably removable from the sliding joint 22 after fluid coupling with the vial 12 through the passageway of the sliding joint 22 without removal of the sliding joint 22 from the tubular connector 18 and without removal of the needle 20 from the tubular connector 18.

Amended claim 1 is directed to a syringe safety device configured to form a fluid coupling between a sealed vial and a syringe and recites, as follows:

> a tubular connector having opposing first and second open axial ends, the first open axial end being adapted to engage an end of a conventional medicine vial with stopper; and
>
> a sliding joint received in the second open axial end of the tubular connector, the sliding joint having opposing first and second open axial ends and a passageway between the first and second open axial ends, the first open axial end being adapted to ~~engage~~ releasably mate with an enlarged, blunt mounting end of a syringe needle, the second axial end of the sliding joint further being adapted to releasably engage at least a releasable needle receiver on a distal end of a barrel of a conventional syringe without a needle, the syringe being releasably removable from the sliding joint after fluid coupling with the vial through the passageway of the sliding joint without removal of the sliding joint from the tubular connector and without the needle.
>
> [underlined emphases added]

Applicants respectfully submit that none of the various embodiments of Neftel teach, suggest or disclose each and every element of amended claim 1 of the present application. Specifically, none of the embodiments of Neftel teach, suggest or disclose a sliding joint received in a tubular connector with a first open axial end adapted to releasably mate with a blunt mounting end of a syringe needle and an opposed second open axial end adapted to releasably engage a releasable needle receiver on a distal end of a barrel of a syringe without a needle. None of the embodiments of Neftel, with the exception of the embodiments of Figs. 3, 4 and 13, permits release of the needle from the syringe such that the needle remains in the tubular connector or sleeve when the syringe is removed from the sliding joint after fluid coupling with the vial, as is claimed in claim 1. Amended claim 1 requires a three piece system such that both the needle and the syringe are both releasably engaged with the sliding joint. The needle in Figs. 3 and 4 in Neftel does not releasably mate with the sliding joint and the sliding joint in Fig. 13 does not releasably engage a releasable needle receiver on a distal end of a barrel of a syringe. In the remaining Neftel embodiments, the needle is mounted directly to the syringe and is not detached from the syringe. Though Applicant's respectfully submit that the tubular segment 60 in Neftel does not include an enlarged, blunt mounting end that engages with a sliding joint, claim 3 has been incorporated into claim 1 to further clarify that the needle in amended claim 1 releasably mates with the sliding joint.

Based upon the above, Applicants respectfully submit that none of the embodiments of the syringe device of Neftel teach, suggest or disclose each and every element of amended claim 1 and respectfully request that the Examiner reconsider and withdraw any rejection of amended claim 1 based upon anticipation by Neftel.

Claim 3 has been incorporated into amended claim 1 and has been therefore cancelled. Claims 2, 4-6, 8-10 and 13-14 are dependent on amended claim 1. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw any rejection of claims 2-6, 8-10, and 13-14 based upon anticipation by Neftel due to their dependence upon claim 1 for the same reasons outlined above.

Claim 7

Claim 7 is even further distinguishable over Neftel.

Amended claim 7 is directed to a syringe safety device configured to form a fluid coupling between a sealed vial and a syringe and recites, as follows:

> a tubular connector having opposing first and second open axial ends, the first open axial end being adapted to engage an end of a conventional medicine vial with stopper;
>
> a sliding joint received in the second open axial end of the tubular connector, the sliding joint having opposing first and second open axial ends and a passageway between the first and second open axial ends, the first open axial end having a needle receiver configured to engage with a bell shaped mating member of a syringe needle, the second axial end of the sliding joint having a needle receiver engaging structure configured to releasably receive a Luer type needle receiver on a distal end of a barrel of a conventional syringe, whereby the sliding joint can be releasably engaged between a releasable syringe needle and a syringe directly releasably engageable with the syringe needle, the syringe being releasably removable from the sliding joint after fluid coupling with the vial through the passageway of the sliding joint without removal of the sliding joint from the tubular connector and without the needle.
>
> [Underlined emphasis added]

Applicants respectfully submit that none of the various embodiments of Neftel teach, suggest or disclose each and every element of currently amended claim 7 of the present application. In addition to the arguments presented above for amended claim 1, none of the embodiments of Neftel teach, suggest or disclose a sliding joint received in a tubular connector having a needle receiver engaging structure configured to releasably receive a Luer type needle receiver on a distal end of a barrel of a conventional syringe. In amended claim 7, the Luer type needle receiver of a conventional syringe is releasably received in the sliding joint and is capable of directly connecting to the needle when the sliding joint is not disposed between the needle and the syringe. Fig. 13 in Neftel is the only embodiment that includes a Luer connection between the syringe and the needle. However, the syringe in Fig. 13 of Neftel is directly secured to the needle within the tubular connector. A sliding joint does not attach between the needle and the needle receiver. The syringe 12' in Fig. 13 has an integral sliding joint that is not releasable and requires a custom syringe.

Based upon the above, Applicants respectfully submit that none of the embodiments of the syringe device of Neftel teach, suggest or disclose each and every element of amended claim 7 and respectfully request that the Examiner reconsider and withdraw any rejection of claim 7 based upon anticipation by Neftel.

Claim Rejections – 35 U.S.C. § 103

The Examiner rejected claims 9, 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Neftel. The Examiner argues that Neftel discloses each and every element of claims 9, 11 and 12 except for providing sealed sterile packaging. The Examiner asserts that it would have been obvious to one skilled in the art to package the components together in sealed sterile packaging. Applicants respectfully traverse this rejection.

Claims 9, 11 and 12 are dependent upon claim 1. As was described above, Applicants respectfully submit that Neftel does not teach, suggest or disclose each and every element of currently pending claim 1. Further, Applicants respectfully submit that even if Neftel was modified to include the sterile packaging, as was proposed by the Examiner, the modified device would not include each and every element of claim 1, wherein the deficiencies of Neftel were outlined in detail above. In addition, Applicants respectfully submit that one having ordinary

skill in the art would not be motivated to modify Neftel to include the above-described elements and there is no motivation in Neftel or in the knowledge of one having ordinary skill in the art to modify Neftel to include the above-listed elements or the sterile packaging claimed in claims 9, 11 and 12, as was proposed by the Examiner.

Based upon the above arguments, Applicants respectfully request that the Examiner reconsider and withdraw any rejection of claims 9, 11 and 12.

CONCLUSION

In view of the foregoing Amendment After Final and remarks, Applicants respectfully submit that the present application, including claims 1-2 and 4-14 as amended, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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